

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

Application Number	10/597,888
Filing Date	August 3, 2006
First Named Inventor	Jeffrey RUBERTI
Art Unit	2627
Examiner Name	Not Yet Assigned
Attorney Docket Number	20780-025

Sheet 1 of 6

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number/Kind Code <sup>2</sup> (If Known)			
	A1	3,875,302	04/01/1975	Inoue	
	A2	4,472,542	09/18/1984	Nambu	
	A3	4,663,358	05/05/1987	Hyon	
	A4	4,772,287	09/20/1988	Ray	
	A5	4,904,260	02/27/1990	Stoy	
	A6	5,047,055	09/10/1991	Bao	
	A7	5,071,437	12/10/1991	Steffee	
	A8	5,260,066	11/09/1993	Wood	
	A9	5,288,503	02/22/1994	Wood	
	A10	5,534,028	07/09/1996	Bao,	
	A11	5,705,296	01/06/1998	Kamauchi	
	A12	5,731,005	03/24/1998	Ottoboni	
	A13	5,880,216	03/09/1999	Tanihara	
	A14	5,976,186	11/02/1999	Bao	
	A15	5,981,826	11/09/1999	Ku	
	A16	6,264,695	07/24/2001	Stoy	
	A17	6,268,405	07/31/2001	Yao	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	†
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (If Known)				
	B1	WO 01/12107 AI	02/22/2001	LAMBRECHT	English	
	B2	WO 02/054978 A2	07/18/2002	LAMBRECHT	English	
	B3	JP 04 338326A	11/25/1992	OKAMURA	W/English Translation	
	B4	JP 03215417A	09/20/1991	YAMAUCHI et al.	W/English Translation	
	B5	EP 1229873	08/14/2002	MARCOLONGO	English	

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Substitute for form 1449/PTO		<b>Complete if Known</b> Application Number: 10/597,688 Filing Date: August 3, 2006 First Named Inventor: Jeffrey RUBERTI Art Unit: 2627 Examiner Name: Not Yet Assigned Attorney Docket Number: 20780-025	
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Sheet	2	of	6

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	C1	AAOS, Musculoskeletal Conditions in the U.S., Feb. 1992-1988, 1992, AAOS	
	C2	Bao, Q.B., & Yuan, H. A., "Nucleus Replacement," Spine, Vol. 27, No. 11, 2002, 1245-1247	
	C3	Bao, Q. & Yuan, H.A., "Prosthetic Disc Replacement: The Future?," Clinical Orthopaedics and Related Research, No. 394, pp 139-145, 2002	
	C4	Zeegeers, W. S., et al, "Artificial disc replacement with the modular type SB Charit III: 2-year results in 50 prospectively studied patients," Eur Spine J, 8:210-217, 1999	
	C5	Wiesel, S.W. et al, "Industrial Low-Back Pain-A Prospective Evaluation of a Standardized Diagnostic and Treatment Protocol," SPINE, Vol. 9, No. 2, 199-203, 1984	
	C6	Vago, R., "Novel Natural Materials for Bone Substitutes and Hard Tissue Remodeling," <a href="http://www.bgu.ac.il/bgn/bone.html">http://www.bgu.ac.il/bgn/bone.html</a>	
	C7	Bao, Q. et al, "The artificial disc: theory, design and materials," Biomaterials Vol. 17, No. 12, (1996) 1157-1167	
	C8	Urushizaki, F. et al, "Swelling and mechanical properties of poly(vinyl alcohol) hydrogels," International Journal of Pharmaceutics, 58 135-142, 1990	
	C9	UPMC Surgeons Implanting Metal Cages into the Spine to Treat Chronic Low Back Pain, Neurosurgery News, 1999, University of Pittsburgh	
	C10	Takeshita, H. et al, "Gelation Process and Phase Separation of PVA Solutions as Studied by a Light Scattering Technique," Macromolecules 32, 7815-7819, 1999	
	C11	Oka, M. et al, "Development of artificial articular cartilage," Proc Instn Mech Engrs Vol. 214 Part H, 59-68, 2000	
	C12	Onuki, A. & Puri, S., "Spinodal decomposition in gels," Physical Review E, Vol. 59, No. 2, Feb. 1999, R1331-R1334	
	C13	Mike, C., "FDA Approves Bone Graft," 2002, <a href="http://www.news.wisc.edu/view.html?get=7640">http://www.news.wisc.edu/view.html?get=7640</a>	
	C14	Takeshita, H. et al, "Small-angle neutron scattering studies on network structure of transparent and opaque PVA gels," Physica B 311 (2002) 78-83	
	C15	Lozinsky, V. I. et al, "Swelling behavior of poly(vinyl alcohol) cryogels employed as matrices for cell immobilization," Enzyme Microb. Technol., Vol. 18, 561-569, 1996	
	C16	Juarez, K.K. & An, H.S., "Artificial Disc Replacement," <a href="http://Spineuniverse.com">Spineuniverse.com</a>	

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Substitute for form 1449/PTO		Complete if Known			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>		Application Number	10/597,688		
		Filing Date	August 3, 2006		
		First Named Inventor	Jeffrey RUBERTI		
		Art Unit	2627		
		Examiner Name	Not Yet Assigned		
Sheet	3	of	6	Attorney Docket Number	20780-025

NON PATENT LITERATURE DOCUMENTS			
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	C17	Kawanishi K. et al, "Thermodynamic consideration of the sol-gel transition in polymer solutions," 35 <sup>th</sup> Annual Meeting of the Society of Polymer Science, Japan, 1986	
	C18	"New Implants Offer Relief of Spine 2001, Medical Device and Diagnostic Industry	
	C19	Takeshita, H., et al, "Spinodal Decomposition and Syneresis of PVA Gel, Macromolecules 2001, 34, 7894-7898	
	C20	Diwan, A. D. et al, "Current Concepts in Intervertebral Disk Restoration," Tissue Engineering in Orthopedic Surgery, Vol. 31, No. 3, pp 453-464, July 2000	
	C21	Peppas, N. A. et al, "Physicochemical Foundations and Structural Design of Hydrogels in Medicine and Biology," Annu. Rev. Biomed. Eng., 02:9-20, 2000	
	C22	Willcox, P. J., et al, "Microstructure of Poly(vinyl alcohol) Hydrogels Produced by Freeze/Thaw Cycling, Journal of Polymer Science: Part B: Polymer Physics, Vol. 37, 3438-3454 (1999)	
	C23	Bray, J.C. & Merrill, E. W., "Poly(vinyl alcohol) Hydrogels for Synthetic Articular Cartilage Material, Biomed. Mater. Res., Vol. 7, pp. 431-443 1973	
	C24	Stammen, J. A., et al, "Mechanical properties of a novel PVA hydrogel in shear and unconfined compression," Biomaterials, 2001 Apr 22 (8), 799-806, abstract only	
	C25	Bray, J.C. & Merrill, E. W., "Poly(vinyl Alcohol) Hydrogels. Formation by Electron Beam Irradiation of Aqueous Solutions and Subsequent Crystallization," Journal of Applied Polymer Science, Vol. 17, pp 3779-3794, 1973	
	C26	Hong, P. et al, "Solvent Effect on Structural Change of Poly(vinyl alcohol) Physical Gels," Journal of Applied Polymer Science, Vol. 69, 2477-2486 (1998)	
	C27	Hong, P. et al, "Effects of Mixed Solvent on Gelation of Poly(vinyl alcohol) Solutions," Journal of Applied Polymer Science, Vol 79, Issue: 6, Date: 7 February 2001, Pages: 1113-1120	
	C28	Hassan C. M. & Peppas N. A., "Structure and Morphology of Freeze/Thawed PVA Hydrogels," Macromolecule, Vol. 33, No. 7, 2472-2479, 2000	
	C29	Griffith, S. L. et al, "A Multicenter Retrospective Study of the Clinical Results of the LINK® SB Charite Intervertebral Prosthesis," SPINE, Vol. 19, No. 16, 1842-1849, 1994	
	C30	Flory, P.J., "Principles of Polymer Chemistry, 1953, Ithaca and London: Cornell University Press	
	C31	de Gennes, P.G., "Scaling Concepts in Polymer Physics," First ed. 1979: Cornell University Press, 72, 113-114	

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	C32	Choi, J. H., et al., "Rheological Properties of Syndiotacticity-Rich Ultrahigh Molecular Weight Poly(vinyl alcohol) Dilute Solution," Journal of Applied Polymer Science, Vol. 82, 569-576 (2001)	
	C33	Doehring, T.C. et al, "Cyclic Load-Displacement Characteristics of Lumber Functional Spinal Units, 46 <sup>th</sup> Annual Meeting, Orthopaedic Research Society, March 12-15, 2000	
	C34	Damshkaln, L. G., et al, "Study of Cryostructuration of Polymer Systems. XV. Freeze-Thaw-Induced Formation of Cryoprecipitate Matter from Low-Concentrated Aqueous Solutions of Poly(vinyl alcohol), Journal of Applied Polymer Science, Vol. 74, 1978-1986 (1999)	
	C35	Darwis, D., et al, "Characterization of poly(vinyl alcohol) hydrogel for prosthetic intervertebral disc nucleus," Radiation Physics and Chemistry 63 (2002) 539-542	
	C36	Gomes, K. et al, "The Effect of Dehydration History on Associating Hydrogels for Nucleus Pulposus Replacement, Society for Biomaterials, 28 <sup>th</sup> Annual Meeting Transactions, 2002	
	C37	Hassan C., M. et al, "Diffusional characteristics of freeze/thawed poly(vinyl alcohol) hydrogels: Applications to protein controlled release from multilaminar devices," European Journal of Pharmaceutics and Biopharmaceutics 49 (2000) 161-165	
	C38	Elias, H.G., "Theta Solvents," Brandrup, J. and E. H. Immergut, Polymer Handbook 3rd Ed., John Wiley & Sons, NY 1989	
	C39	Hassan, C., M., & Peppas, N.A., "Cellular PVA Hydrogels Produced by Freeze/Thawing," Journal of Applied Polymer Science, Vol. 76, 2075-2078 (2000)	
	C40	Lozinsky, V. I., et al, "Study of Cryostructuration of Polymer Systems, XIV. Poly(vinyl alcohol) Cryogels: Apparent Yield of the Freeze-Thaw-Induced Gelation of Concentrated Aqueous Solutions of the Polymer," Journal of Applied Polymer Science, Vol. 77, 1822-1831 (2000)	
	C41	Nakane, K., et al, "Properties and Structure of Poly(vinyl alcohol)/Silica Composites, Journal of Applied Polymer Science, Vol. 74, 133-138 (1999)	
	C42	Hassan, C., M. et al., "Modeling of crystal dissolution of poly(vinyl alcohol) gels produced by freezing/thawing process," Polymer 41 (2000) 6729-6739	

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	C43	Hickey, A. S. & Peppas N.A., "Solute diffusion in poly(vinyl alcohol)/poly(acrylic acid) composite membranes prepared by freezing/thawing techniques, Polymer, Vol. 38 No. 24 1997 5931-5936	
	C44	Li, J. K., et al, "Poly(vinyl alcohol) nanoparticles prepared by freezing-thawing process for protein/peptide drug delivery," Journal of Controlled Release 56 (1998) 117-126	
	C45	Lozinski V. I. & Savina I. N., "Study of Cryostructuring of Polymer Systems: 22. Composite Poly(vinyl alcohol) Cryogels Filled with Dispersed Particles of Various Degrees of Hydrophilicity/Hydrophobicity," Colloid Journal, Vol. 64, No. 3, 2002, 336-343	
	C46	Lozinsky, V. I. & Damshkaln L. G., "Study of Cryostructuring of Polymer Systems. XVII. Poly(vinyl alcohol) Cryogels: Dynamics of the Cryotropic Gel Formation, Journal of Applied Polymer Science, Vol. 77, 2017-2023 (2000)	
	C47	Marolongo, M., et al, "Novel Hydrogel Copolymers for Intervertebral Disc Replacement," Sixth World Biomaterials Congress Transactions, 2000	
	C48	Mongia, N.K., et al, "Mucoadhesive poly(vinyl alcohol) hydrogels produced by freezing/thawing processes: Applications in the development of wound healing systems," J. Biomater. Sci. Polymer Edn, Vol. 7, No. 12, pp. 1055-1064 (1996)	
	C49	Narasimhan, B. & Peppas, N.A., "Molecular Analysis of Drug Delivery Systems Controlled by Dissolution of the Polymer Carrier," Journal of Pharmaceutical Sciences, Vol. 86, No. 3, March 1997	
	C50	Norton, B. K, et al, "Mechanical Evaluation of a Structural Hydrogel for Use as a Spinal Disc Nucleus," Sixth World Biomaterials Congress Transactions, 2000	
	C51	Ogata, N., et al., "Poly(vinyl alcohol)-clay and Poly (ethylene oxide)-clay Blends Prepared Using Water as Solvent," Journal of Applied Polymer Science, Vol. 66, 573-581 (1997)	
	C52	Peppas, N.A. & Stauffer, S. R., "Reinforced uncrosslinked poly (vinyl alcohol) gels produced by cyclic freezing-thawing processes: a short review," Journal of Controlled Release, 16 (1991) 305-310	
	C53	Strawhecker, K.E. & Manias E., "AFM of Poly(vinyl alcohol) Crystals Next to an Inorganic Surface," Macromolecules, 2001, 34, 8475-8482	
	C54	Strawhecker, K.E. & Manias, E., "Structure and Properties of Poly(vinyl alcohol)/INA+ Montmorillonite Nanocomposites," Chem. Mater, 2000, 12, 2943-2949	
	C55	Takahashi, N., et al, "Effects of cosolvency on gelation of poly(vinyl alcohol) in mixed solvents of dimethyl sulfoxide and water," Polymer 44 (2003) 4075-4078	

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